UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

Note to Reader
August 7, 1998

Background: As part of its effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), which is designed to ensure that the United States continues to have the safest and most abundant food supply, EPA is undertaking an effort to open public dockets on the organophosphate pesticides. These dockets will make available to all interested parties documents that were developed as part of the U.S. Environmental Protection Agency's process for making reregistration eligibility decisions and tolerance reassessments consistent with FQPA. The dockets include preliminary health assessments and, where available, ecological risk assessments conducted by EPA, rebuttals or corrections to the risk assessments submitted by chemical registrants, and the Agency's response to the registrants' submissions.

The analyses contained in this docket are preliminary in nature and represent the information available to EPA at the time they were prepared. Additional information may have been submitted to EPA which has not yet been incorporated into these analyses, and registrants or others may be developing relevant information. It's common and appropriate that new information and analyses will be used to revise and refine the evaluations contained in these dockets to make them more comprehensive and realistic. The Agency cautions against premature conclusions based on these preliminary assessments and against any use of information contained in these documents out of their full context. Throughout this process, if unacceptable risks are identified, EPA will act to reduce or eliminate the risks.

There is a 60 day comment period in which the public and all interested parties are invited to submit comments on the information in this docket. Comments should directly relate to this organophosphate and to the information and issues

available in the information in this docket. Once the comment period closes, EPA will review all comments and revise the risk assessments, as necessary.

These preliminary risk assessments represent an early stage in the process by which EPA is evaluating the regulatory requirements applicable to existing pesticides. Through this opportunity for notice and comment, the Agency hopes to advance the openness and scientific soundness underpinning its decisions. This process is designed to assure that America continues to enjoy the safest and most abundant food supply. Through implementation of EPA's tolerance reassessment program under the Food Quality Protection Act, the food supply will become even safer. Leading health experts recommend that all people eat a wide variety of foods, including at least five servings of fruits and vegetables a day.

Note: This sheet is provided to help the reader understand how refined and developed the pesticide file is as of the date prepared, what if any changes have occurred recently, and what new information, if any, is expected to be included in the analysis before decisions are made. **It is not meant to be a summary of all current information regarding the chemical.** Rather, the sheet provides some context to better understand the substantive material in the docket (RED chapters, registrant rebuttals, Agency responses to rebuttals, etc.) for this pesticide.

Further, in some cases, differences may be noted between the RED chapters and the Agency's comprehensive reports on the hazard identification information and safety factors for all organophosphates. In these cases, information in the comprehensive reports is the most current and will, barring the submission of more data that the Agency finds useful, be used in the risk assessments.

Jack Housenger, Acting Director
Special Review and Reregistration
Division

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04/03/98

MEMORANDUM

SUBJECT: Terbufos. List A Reregistration Case No. 0109/Chemical ID No. 105001. Chronic Dietary Risk Analysis Based on the 3/19/98 Anticipated Residues. No MRID #. DP Barcode No. D244364.

FROM: Christina B. Swartz, Chemist
Reregistration Branch 1
Health Effects Division (7509C)

THRU: Whang Phang, Ph.D., Branch Senior Scientist
Reregistration Branch 1
Health Effects Division (7509C)

TO: Lisa Nisenson/Robert McNally (PM 60)
Special Review Branch
Special Review and Reregistration Division (7508W)

Action Requested

In conjunction with the preparation of a revised HED RED chapter for terbufos, an anticipated residues assessment was conducted using % crop treated data from BEAD and field trial data submitted in support of registration and reregistration. A copy of the anticipated residue memo dated 3/19/98 is attached (W. Hazel, Barcode D244268). A revised chronic dietary risk analysis using the Dietary Risk Evaluation System (DRES) has been requested, using the new anticipated residues and the % crop treated data from BEAD.

Toxicological Information

The HED Hazard Identification Assessment Review Committee met on 9/8/97 (memo issued on 9/25/97) to evaluate the terbufos toxicology database with respect to the reproductive, developmental and neurotoxicity data and the application of the additional safety factor required under FQPA. The HED RfD committee had met 5/22/96 and 5/23/96 (memo issued 7/1/96) to reconsider the reference dose (RfD) used in the Agency's chronic dietary risk assessments.

An RfD of 0.00005 mg/kg/day was derived from the NOEL of 0.005 mg/kg/day and an Uncertainty Factor (UF) of 100 (10 for intra-species and 10 for inter-species variation). The

NOEL was from a 28-day study in dogs, in which the LOEL was based on inhibition of plasma cholinesterase activity observed at 0.015 mg/kg/day. Additional 6-month and 1-year feeding studies in dogs were considered to be co-critical in the selection of the NOEL. The HED HIARC recommended that the additional 10X FQPA factor be reduced to 3X. The additional factor has not been applied to the RfD for this assessment, since the process for applying the safety factor is still evolving in HED/OPP. Studies submitted to the Agency have indicated there is no evidence of carcinogenicity in rats and mice.

Residue Information

Tolerances have been established for terbufos residues in bananas, sugar beet commodities, corn commodities and sorghum commodities; in addition, a time-limited tolerance was established for residues in coffee, but expired 12/15/97 [40 CFR §180.352].

As stated above, an anticipated residues assessment was conducted, with the following results:

Anticipated Residues and Percent Crop Treated for Chronic Risk Assessment.

Crop/Food	Anticipated Residue (ppm)	Percent Crop Treated (max.)
Banana	0.025	26 %
Field corn and all processed products	0.005	11 %
Popcorn	0.005	11 %
Sorghum and any processed products	0.025	4 %
Sugar beet (sugar)	0.001	37 %
Sweet corn	0.005	9 %

No concentration or reduction factors are necessary for the DRES analysis. Refer to the 3/19/98 W. Hazel memo for details regarding the derivation of the anticipated residues.

Results

The table shown below demonstrates the %RfD (chronic dietary risk for terbufos) occupied by the existing uses for various population subgroups using tolerance level residues (TMRC) and using anticipated residues with the percent crop treated incorporated (ARC). Note that the %RfD values in the table below include the use on coffee. When coffee is taken out of the assessment, the %RfD for the general US population decreases to 4.9 %RfD, while the %RfD for children 1-6 decreases to 11.6 %RfD (there was no consumption for coffee in non-nursing infants <1 year) [note that the TMRC was used for coffee, since there were no data for % crop treated available,

and since the tolerance was used for the residue level in coffee].

Summary of Terbufos Chronic Dietary Risk for Several Population Subgroups Determined Using DRES (Dietary Risk Evaluation System)

Population Subgroup	%RfD Using Tolerances (TMRC)	%RfD Using Anticipated Residues (ARC)*
General US Population	152.6	8.5 (2.9)
Non-nursing infants (<1 yr)	397.9	15.8 (14.1)
Children 1-6	351.2	11.7 (9.5)

* The numbers in parentheses indicate the %RfD consumed by the use on/consumption of bananas.

Discussion

The chronic dietary risk appears to be below the Agency's level of concern based on the % of the reference dose consumed by the registered uses for the most highly exposed population subgroups. Note that the anticipated residues were generated using field trial data. The low level of confidence in the banana residue data (refer to the 3/19/98 W. Hazel memo) is significant, since a large percentage of the RfD is consumed by the use on/consumption of bananas for the most highly exposed subgroups.

Note that an additional safety factor potentially required for this risk assessment under FQPA has not been applied to the assessment of dietary risk.

Attachments: (1) 3/19/98 Anticipated Residue Assessment (W. Hazel, Barcode No. D 244268)
(2) Chronic dietary risk analysis conducted using DRES

DRES Secondary Review: B. Steinwand:4/3/98

cc (with attachments): Reviewer (CSwartz); William Hazel (7509C/HED
cc (without attachments): List A Rereg. File; SF
7509C:CSwartz:RRB1:CM2:Rm 804F:703 305 5877:4/1/98